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Please find below and/or attached an Office communication concerning this application or proceeding.

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1,5-6, 9, 14-16 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 as evidenced by Bifidobacterial NPL and DHA NPL.

Regarding claim 1,6,9,14,16, Carlson teaches a “formula” (infant, see column 3, line 47 and line 65) comprising protein, carbohydrates, and lipids (column 11, line 27). As seen in table IV, column 13, lines 5-31, arachidonic acid and docosahexaenoic acid may be present in 0.41 weight % (22 mg) and 0.14 weight % (7 mg) respectively (column 13, lines 36-41). Additionally, the amounts of arachidonic acid may range from 1.0-60 mg (column 3, lines 66-67) and the amounts of docosahexaenoic acid may range from 0.25-35 mg (column 4, line 1) in the formula.

Carlson fails to explicitly teach docosahexaenoic acid being present in an amount of 0.2 – 0.5 % of the fatty acids and the formula further comprising a probiotic.

Although Carlson fails to explicitly teach arachidonic acid and docosahexaenoic acid both being present in the formula wherein the docosahexaenoic acid amount is 0.2-0.5%, Carlson does teach that the amount of docosahexaenoic acid may range from 0.25 – 35 mg as discussed previously (the 0.14% discussed previously pertains to 7 mg being present.) In light of these teachings, one of ordinary skill in the art would have found it obvious to slightly increase the docosahexaenoic acid content to 7 mg (which results in 0.14%) to a slightly higher amount in order to boost the brain health boosting properties (produce known effects) of the formula (see docosahexaenoic acid NPL). Also, in light of the teachings discussed previously, the claimed range would have been discoverable by routine experimentation by one of ordinary skill in the art seeking to boost the brain health enhancing properties of the “formula”.

Halpin-Dohnalek teaches probiotics such as lactobacillus (**column 3, lines 44-48**). the formula may additionally comprise bifidobacterium also as seen in **column 3**,

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lines 35-36) for use in an infant formula (**column 4, lines 23-25**). It would be obvious to one of ordinary skill in the art at the time that the invention was made to modify the infant formula of Carlson (which reduces the incidence of necrotizing enterocolitis, **column 3, lines 45-50 of Carlson**) to further comprise the probiotics of Halpin-Dohnalek to further enhance the formula's disease fighting properties (**column 1, lines 45-50 of Halpin-Dohnalek**). (Further, *Necrotizing enterocolitis is a gastrointestinal disease and probiotics such as bifidobacteria are known to reduce the risk of this disease (see NPL Bifidobacterial supplementation reduces the incidence of necrotizing enterocolitis in a neonatal rat model)*)

Additionally, referring to "strengthening natural immune defenses" and "reducing... morbidity" recited in claims 14 and 16 respectively, the formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Referring to claim 5, in the cited embodiment discussed in examiners address of claim 1, the arachidonic acid and the docosahexaenoic acid would be in an ratio of 1:0.34. If this ratio is scaled by a multiple of 1.2, the resulting equivalent ratio would be 1.2:0.4. Applicant's claimed range ranges from 0.8:1 - 1.2:1. Even though the range of the composite invention is not within the claimed range, slightly increasing the amount of docosahexaenoic acid in order to improve the healthiness of the composite invention (Docosahexaenoic acid is known to help with brain growth of infants (see DHA NPL).)

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would have been obvious and thus it is considered that discovering the claimed range would have been obvious in light of the composite invention.

Referring to claim 15, Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the composite invention would be nutritionally complete.

Claim 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata as evidenced by Bifidobacterial NPL.

Referring to claim 7, the references teach the invention of claim 6 and in particular, Halpin-Dohnalek teaches Bifidobacterium infantis(column 3, line 46) however Halpin-Dohnalek does not explicitly teach Bifidobacterium longum BB 536.

Ogata teaches that it is known in the art to add Bifidobacterium longum BB536 (1st paragraph of Ogata) to food product (see Yogurt section). It would have been obvious to one having ordinary skill in the art at the time of the invention to add Bifidobacterium longum BB536 to the formula of the composite invention discussed previously since this would enhance the health boosting properties of the formula (as

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can be seen in the second paragraph of the introduction, Bifidobacterium longum BB536 enhances immunity, bone density, and reduces cancer risk).

Claim 8 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1 as evidenced by Bifidobacterial NPL.

Referring to claim 8, the references teach the invention of claim 6 and in particular, Halpin-Dohnalek teaches lactobacillus reuteri (column 3, line 45) however Halpin-Dohnalek does not explicitly teach lactobacillus rhamnosus GG.

Van Hoey-De-Boer teaches that it is well known in the art to add lactobacilli such as lactobacillus rhamnosus GG (paragraph 18) to food products (paragraph 0003). It would have been obvious to one having ordinary skill in the art at the time of the invention to add lactobacillus rhamnosus GG to the composite invention discussed previously since this would enhance the health boosting properties of the invention (see paragraphs 17-20 and 3-4. This probiotic has therapeutic effects on gastrointestinal diseases).

Claim 10 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Klaske Anna Van Hoey-De-Boer, EP 0904784 A1

and Effect of Bifidobacterium longum BB536 yogurt administration on the intestinal environment of healthy adults by T. Ogata as evidenced by Bifidobacterial NPL.

Referring to claim 10, see examiner's address of claims 6, 8-9 for why this limitation would have been obvious.

Claims 11-13, 17-21 rejected under 35 U.S.C. 103(a) as being unpatentable over Susan E. Carlson, US-Patent 6,306,908 in view of Margaret Ione Halpin-Dohnalek, US-Patent 5,902,578 and further in view of Zdenek Kratky, US-Patent 6,777,391 as evidenced by Threonine NPL and Bifidobacterial NPL.

Referring to claim 11 and 17, the references teach the invention of claim 1 and in particular, Carlson teaches whey protein concentrate (column 11, line 15)

Carlson does not explicitly teach modified sweet whey proteins with no CGMP or reduced CGMP.

Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (**column 2, lines 36-37**). It would have been obvious to one of ordinary skill in the art at the time of the invention to replace the whey protein concentrate of Kratky with the modified sweet whey protein to reduce the threonine content of the protein (**column 2, lines 36-39**). It is widely known that threonine increases brain glycine which in turn affects neurotransmitter balance in the brain and

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thus has negative consequences for brain development in the postnatal stages of life (and further, threonine levels are sought to be reduced in infant products). **(see**

Threonine NPL)

Referring again to **claim 11**, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Kratky teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Kratky overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

“The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages”, In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Referring to claim 12, Kratky teaches from 6 to 50% whey protein (column 2, line 22) and later, Kratky teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 60% falls does not fall within this range however it would

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have been obvious to one having ordinary skill in the art at the time the invention was made to adjust the protein percentages, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272,205 USPQ 215 (CCPA 1980). Additionally, increasing the protein amount would boost the healthiness of the formula (proteins are well known to help with mammal growth).

Referring to claim 13, Kratky teaches proteins present at less than 2 g/100 kcal (*column 9, line 35*).

Referring to claim 18, Krathy teaches that a preferred embodiment addresses the nutritional needs and provide for healthy growth of an infant (column 2, line 63-64). This is considered to provide complete nutritional needs of a baby or infant. Also, Carlson teaches that his formula is nutritionally complete (column 7, line 40) so the formula of the references would be nutritionally complete.

Referring to claim 19, the resulting composition of the references is considered to be capable of promoting healthy mental development in a preterm infant since it contains all of the components of the claimed composition.

The references do not explicitly teach using the composition to strengthen natural immune defenses of an infant or baby by feeding it to the preterm infant however, when

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the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F.2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978). Further, while the references do not show a specific recognition of that result, its discovery by appellants is tantamount only to finding a property in the old composition." 363 F.2d at 934, 150 USPQ at 628. Additionally, the formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Referring to claim 20, Krathy teaches proteins present at 1.83 g/100 kcal which falls within the claimed range (**column 9, line 35**).

Referring to claim 21, Krathy teaches from 6 to 50% whey protein (column 2, line 22) and later, Krathy teaches that the whey protein can be sweet whey protein (column 2, line 36). At least 40% falls within this range. Furthermore, to one of ordinary skill in the art at the time the invention was made would have considered the invention to have been obvious because the compositional proportions taught by Krathy overlap the instantly claimed proportions and therefore are considered to establish a prima facie case of obviousness. It would have been obvious to one of ordinary skill in the art to select any portion of the disclosed ranges including the instantly claimed ranges from the ranges disclosed in the prior art reference, particularly in view of the fact that;

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"The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages", In Re Peterson 65 USPQ2d 1379 (CAFC 2003).

Also, In e Geisler 43 USPQ2d 1365 (Fed. Cir. 1997); In re Woodruff, 16 USPQ2d 1934 (CCPA 1976); In re Malagari, 182 USPQ 549, 553 (CCPA 1974) and MPEP 2144.05.

Response to Arguments

Applicant argues that Carlson and fail to teach or mention any percentages or the requirement of specific percentages of ARA and DHA in the total fatty acids in the lipid source as is required, in part by the present claims (see pages 6 and 7). Carlson teaches a "formula" (infant, see column 3, line 47 and line 65) comprising protein, carbohydrates, and lipids (column 11, line 27). As seen in table IV (the table is based on the lipids), column 13, lines 5-31, arachidonic acid and docosahexaenoic acid may be present in 0.41 weight % (22 mg) and 0.14 weight % (7 mg) respectively (column 13, lines 36-41). Additionally, the amounts of arachidonic acid may range from 1.0-60 mg (column 3, lines 66-67) and the amounts of docosahexaenoic acid may range from 0.25-35 mg (column 4, line 1) in the formula. Although Carlson fails to explicitly teach arachidonic acid and docosahexaenoic acid both being present in the formula wherein the docosahexaenoic acid amount is 0.2-0.5%, Carlson does teach that the amount of

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docosahexaenoic acid may range from 0.25 - 35 mg as discussed previously (the 0.14% discussed previously pertains to 7 mg being present.) In light of these teachings, one of ordinary skill in the art would have found it obvious to slightly increase the docosahexaenoic acid content to 7 mg (which results in 0.14%) to a slightly higher amount in order to boost the brain health boosting properties (produce known effects) of the formula (see docosahexaenoic acid NPL). Also, in light of the teachings discussed previously, the claimed range would have been discoverable by routine experimentation by one of ordinary skill in the art seeking to boost the brain health enhancing properties of the "formula". (Additionally, adjusting other components of the formula would effect the weight percentages of the individual components.

Applicant also argues that Carlson fails to teach promoting the immune system (see page 7). The formula of the composite invention would "strengthen" the immune defenses and reduce morbidity in infants since it would it would reduce the risk of conditions such as necrotizing enterocolitis (an infant infection).

Applicant also argues that Halpin-Dohnalek and Kraty fail to remedy the deficiencies of Carlson (see page 7). Halpin-Dohnalek teaches probiotics such as lactobacillus (column 3, lines 44-48. the formula may additionally comprise bifidobacterium also as seen in column 3, lines 35-36) for use in an infant formula (column 4, lines 23-25). Carlson doesn't teach probiotics and thus Halpin-Dohnalek was considered to remedy this lacking feature. Kratky teaches sweet whey proteins that have been modified by the removal of CGMP from the protein (column 2, lines 36-

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37). Carlson doesn't teach sweet whey proteins and thus Kratky was considered to remedy this lacking feature.

Applicant also argues that the references can not be combined to overcome the deficiencies of Carlson because each of the references is geared towards combating different problems (see page 8). In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The references were used for the purposes stated in the office action.

Applicant also argues that Haplin-Dohnalek is drawn to treatment of older children(see page 9) however Haplin Dohnalek states that the invention can be used with infants (abstract). Applicant also argues that probiotics *Lactobacillus reuteri* and *Lactobacillus acidophilus* are not recommended by the WHO for consumption by children under the age of 3. The probiotics of Haplin Dohnalek can be used in a nutritionally complete infant formula and thus this argument is not sufficient to overcome the rejection (see abstract of Haplin-Dohnalek).

Applicant argues that Kankaanpaa (reference provided by applicant) teaches that one of ordinary skill would have been deterred from combining probiotics and PUFA's (see page 9). The Kankaanpa reference does not appear to establish that combining probiotics with PUFA's would be disadvantageous in the references cited by examiner.

In response to applicant's arguments against the references individually (see page 10, all of the arguments. The references were only used to teach concepts in the primary reference that were lacking), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning (see page 11), it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971)

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PRESTON SMITH whose telephone number is (571)270-7084. The examiner can normally be reached on Mon-Th 6:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Drew E Becker/
Primary Examiner, Art Unit 1782

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